IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

DAVID GRIFFIN

Plaintiff,

v.

JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER, INC., JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., ETHICON, INC., ETHICON ENDO-SURGERY, INC., ETHICON ENDO-SURGERY, LLC, and ETHICON US, LLC,

Defendants.

Civil Action No. 2:21-cv-134

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, David Griffin, by and through his undersigned counsel, and state as his Complaint for Damages against JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER, INC., JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., ETHICON, INC., ETHICON ENDO-SURGERY, INC., ETHICON ENDO-SURGERY, LLC, and ETHICON US, LLC (hereinafter collectively "Defendants") for personal injuries suffered as a result of Defendants' defective and unreasonably dangerous product, the Endoscopic Curved Intraluminal Stapler, 29 mm diameter, No. ECS29A (hereafter ILS-No. ECS29A), and state as their claims and allegations, as follows:

I. INTRODUCTION

1. This is an action for the serious and permanent injuries incurred by the Plaintiff resulting from the promotion, sale, manufacture and distribution of an unreasonably dangerous and defective medical device product known generally as the Endoscopic Curved Intraluminal Stapler ("ILS").

2. Defendants are manufacturers of medical devices, including the ILS.

3. The ILS is used in lieu of suturing during various surgeries, for example to create connections between bodily structures, such as anastomoses, or to seal off resections.

4. Defendants are subsidiaries of Johnson & Johnson and according to Johnson & Johnson and its website, the ILS are "designed to promote healing, more tissue control and less tension on the anastomosis, with distinct audible and tactile feedback during firing."[1]

5. Further, the staplers "are designed to deliver optimal compression needed for a secure anastomosis and effective perfusion to promote healing."[2]

6. Defendants' staplers are designed in such a way to give audible and tactile feedback during the firing of the staple to confirm the firing and proper securing of the staple to ensure staple line integrity.

7. As the FDA has explained, "[w]hen the washer is cut, confirming completion of the firing cycle, the surgeon experiences an audible and tactile crunch."[3]

8. On or around March 6, 2018, a shift in the manufacturing of the ILS occurred.

9. As a result of this shift, several models of the Defendants' ILS manufactured from March of 2018 to March 6, 2019 (when the line was shut down) were unable to sufficiently fire the washers, causing uncut washers and malformed staples that compromised the staple line integrity.

10. During this time, 92,496 affected Ethicon ILS were produced and sold in the United States.[4]

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[1] *ETHICON Circular Staplers,* attached as Exhibit 1.
[2] *Id.*
[3] *Ethicon Recalls Circular Staplers for Insufficient Firing and Failure to Completely Form Staples,* attached as Exhibit 2.
[4] *Id.*

11. As the FDA explained in their recall notice, "[f]ailure to cut the washer suggests complete 360-degree staple line failure."[5]

12. Such a failure can cause a host of medical issues, including but not limited to: "death, sepsis, bleeding, the need for permanent ostomy 'bag,' life-long nutritional and digestive issues, leak in the closure (anastomotic leak), additional surgeries, need for additional closures (anastomoses), need for antibiotics, and the need for additional imaging studies."[6]

13. Defendants have long known of the risks of serious injury and death associated with its surgical staplers like the one used on Plaintiff. Between January 2011-March 2018, over 41,000 adverse events were reported with these devices—including over 360 deaths.[7]

14. Despite this information and the potential for serious injury, Defendants failed to maintain quality systems and Current Good Manufacturing Practices (hereinafter "CGMP's") to ensure that its ILS would not have any manufacturing defects and expose patients to risks of serious injury or death when used as intended by the surgeon.

15. As a result, Defendants' ILS was sold for a year despite the dangerous manufacturing defects present in these devices.

16. Defendants' failure to establish effective Post Marketing Safety Surveillance ("PMSS") complaint systems, Adverse Event ("AE") reporting, and Corrective and Preventive Actions ("CAPA") follow-up and investigation allowed a serious manufacturing defect to go unreported for over a year after the defective lots of ILS were released to the U.S. public.

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[5] *Id.*
[6] *Id.*
[7] *Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers, (hereafter "Safe Use"),* attached as Exhibit 3.

17. Any patient who underwent a medical procedure with one of the affected curved ILS manufactured by Defendants from March 6, 2018 to March 6, 2019 were exposed to a serious risk of death or severe injuries.

18. On or around April 11, 2019, a voluntary recall of ILS-No. ECS29A occurred, along with the following product numbers: CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, and ECS33A.[8]

19. On or around May 15, 2019, the FDA issued a Class I Recall for each of 8 ILS devices listed above and others listed below:[9]

> Curved Intraluminal Staplers, 29 mm diameter, No. CDH29A
> Straight Intraluminal Staplers, 21 mm diameter, No. SDH21A
> Curved Intraluminal Staplers, 21 mm diameter, No. CDH21A
> Straight Intraluminal Staplers, 25 mm diameter, No. SDH25A
> Endoscopic Curved Intraluminal Stapler, 21 mm diameter, No ECS21A
> Endoscopic Curved Intraluminal Stapler, 33 mm diameter, No. ECS33A
> Straight Intraluminal Staplers, 33 mm diameter, No. SDH33A
> Curved Intraluminal Staplers, 33 mm diameter, No. CDH33A
> Curved Intraluminal Staplers, 25 mm diameter, No. CDH25A
> Endoscopic Curved Intraluminal Stapler, 29 mm diameter, No. ECS29A

20. For each of the recalls listed above, the FDA named "Ethicon Endo-Surgery Inc." at 4545 Creek Road, Blue Ash, Ohio as the "Recalling Firm/Manufacturer," for all regulatory purposes related to the device.

21. The FDA named agents of or employees of Ethicon Endo-Surgery Inc. in Blue Ash, Ohio as its "correspondent" of all the devices listed above for regulatory purposes.

22. Unfortunately, neither Plaintiff David Griffin nor his surgeon were afforded any knowledge or warning of the defects and dangers associated with the recalls before an Ethicon ILS-No. ECS29A was used in Plaintiff's surgery.

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[8] *See, e.g.*, Exhibit 4, Ethicon Recall Letter.
[9] *See FDA Spreadsheet of Recalled Staplers*, attached as Exhibit 5.

II. PARTIES

A. PLAINTIFF.

23. DAVID GRIFFIN is a citizen of the United States and Vermont, currently residing in Proctor, Vermont.

B. DEFENDANT ETHICON ENDO-SURGERY, INC.

24. ETHICON ENDO-SURGERY, INC. (hereinafter "Ethicon Endo-Surgery") is incorporated in the State of Ohio. It lists its principal office in its current corporate filings with the Secretary of State of Ohio to be at 4545 Creek Road, Blue Ash, Hamilton County, Ohio.

25. Ethicon Endo-Surgery is a subsidiary of Johnson & Johnson.[10]

26. Ethicon Endo-Surgery, in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS.

27. Ethicon Endo-Surgery and its employees, in coordination with the other Defendants, were involved in the manufacture, distribution, sales, marketing, regulatory management, design and related services of such medical products, specifically including the ILS-No. ECS29A alleged to have caused injury here.

28. Defendant Ethicon Endo-Surgery is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent bodily injury to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

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[10] *Subsidiaries*, SEC, https://www.sec.gov/Archives/edgar/data/200406/000020040619000009/ex21-subsidiariesxform10xk.htm (last accessed Apr. 12, 2021).

29. At all times relevant to this action, Ethicon Endo-Surgery has conducted substantial business in Vermont. Plaintiff's causes of action also arise out of specific conduct occurring in Vermont.

30. Ethicon Endo-Surgery is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, Vermont 05633. Service individually and by the Secretary of State should be upon Defendant Ethicon Endo-Surgery at its principal place of business at 4545 Creek Road, Blue Ash, Ohio 45242.[11]

C. DEFENDANT ETHICON, INC.

31. ETHICON, INC. (hereinafter "Ethicon") had at all times relevant to this Complaint its principal place of business at Highway 22, Somerville, New Jersey, 08876.

32. Ethicon is a subsidiary of Johnson & Johnson.[12]

33. Ethicon, in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS-No. ECS29A.

34. Ethicon and its employees, in coordination with the other Defendants, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and related services of such medical products, specifically including the ILS-No. ECS29A alleged to have caused injury here.

35. Defendant Ethicon is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent bodily injury

[11] 12 V.S.A. § § 855. 856. & 913(b); *Bard Bldg. Supply Co. v. United Foam Corp.*, 400 A.2d 1023, 1024 (Vt. 1979).
[12] *See* FN 10, *supra.*

to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

36. At all times relevant to this Complaint, Ethicon has conducted substantial business in Vermont. Plaintiff's causes of action also arise out of specific conduct occurring in Vermont.

37. Ethicon is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, Vermont 05633. Service individually and by the Secretary of State should be upon Defendant Ethicon at its principal place of business at Highway 22, Somerville, New Jersey, 08876.[13]

D. DEFENDANT JOHNSON & JOHNSON.

38. JOHNSON & JOHNSON is the parent corporation of the Johnson & Johnson family of companies, organized and existing under the laws of the State of New Jersey. Johnson & Johnson's principal place of business is at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

39. Johnson & Johnson, in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS-No. ECS29A.

40. Johnson & Johnson and its employees, in coordination with the other Defendants, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and related services of such medical products, specifically including the ILS-No. ECS29A alleged to have caused injury here.

41. Defendant Johnson & Johnson is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent

[13] *See* FN 11, *supra.*

bodily injury to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

42. At all times relevant to this Complaint, Johnson & Johnson has conducted substantial business in Vermont. Plaintiff's causes of action also arise out of specific conduct occurring in Vermont.

43. Johnson & Johnson is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, Vermont 05633. Service individually and by the Secretary of State should be upon Defendant Johnson & Johnson at its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.[14]

E. DEFENDANT JOHNSON & JOHNSON CONSUMER, INC.

44. JOHNSON & JOHNSON CONSUMER, INC. (hereinafter "J&J Consumer") had at all times relevant to this Complaint its principal place of business at 199 Grandview Road, Skillman, New Jersey 08558.

45. J&J Consumer is a subsidiary of Johnson & Johnson.[15]

46. J&J Consumer in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS-No. ECS29A.

47. J&J Consumer and its employees, in coordination with the other Defendants, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and related services of such medical products, specifically including the ILS-No. ECS29A alleged to have caused injury here.

[14] *See* FN 11, *supra.*
[15] *See* FN 10, *supra.*

48. Defendant J&J Consumer is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent bodily injury to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

49. At all times relevant to this Complaint, J&J Consumer has conducted substantial business in Vermont. Plaintiff's causes of action also arise out of specific conduct occurring in Vermont.

50. J&J Consumer is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, Vermont 05633. Service individually and by the Secretary of State should be upon Defendant Ethicon at its principal place of business at 199 Grandview Road, Skillman, NJ 08558.[16]

F. DEFENDANT JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.

51. JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC. (hereinafter "J&J Health") had at all times relevant to this Complaint its principal place of business at 425 Hoes Lane, Piscataway, New Jersey 08855.

52. J&J Health is a subsidiary of Johnson & Johnson.[17]

53. J&J Health in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS-No. ECS29A.

54. J&J Health and its employees, in coordination with the other Defendants, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and

[16] *See* FN 11, *supra.*
[17] *See* FN 10, *supra.*

related services of such medical products, specifically including the ILS-No. ECS29A alleged to have caused injury here.

55. Further, J&J Health is registered to business in Vermont as a foreign corporation.[18]

56. J&J Health is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent bodily injury to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

57. At all times relevant to this Complaint, J&J Health has conducted substantial business in Vermont. Plaintiff's causes of action also arise out of specific conduct occurring in Vermont.

58. J&J Health has an address registered to be served and do business in the State of Vermont at CT Corporation System, 17 G W Tatro Drive, Jeffersonville, Vermont, 05464.

G. DEFENDANT ETHICON ENDO-SURGERY, LLC.

59. ETHICON ENDO-SURGERY, LLC (hereinafter "EES") is domiciled in the State of Delaware and its principal place of business is in Puerto Rico.

60. EES' Certificate of Authorization to do Business as a Foreign Corporation filed with the Puerto Rico Registry of Corporations and Entities lists its designated office address in Puerto Rico as 475 Street C Los Frailes Industrial Park, Suite 401, Guaynabo, Puerto Rico 00969 and its Corporate Domicile as 1209 Orange Street, Wilmington, Delaware 19801.

61. EES is a subsidiary of Johnson & Johnson.[19] EES is a single member LLC owned 100% by Ethicon Endo-Surgery. In the alternative, EES' sole member is one of the Johnson &

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[18] *See Vermont Secretary of State*, https://bizfilings.vermont.gov/online/BusinessInquire/BusinessInformation?businessID=361258 (last accessed Apr. 12, 2021).
[19] *See* FN 10, *supra*.

Johnson family of companies, or is a combination of the J&J "family" members, and all in the "family" are not citizens/domiciled or headquartered in the forum state of Vermont.

62. EES, in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS.

63. EES, and its employees, in coordination with the other Defendants herein, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and related services of such medical products in the United States, and specifically the ILS-No. ECS29A alleged to have caused injury here.

64. EES is subject to the personal jurisdiction of this Court because of the claims stated in this Complaint alleging, to wit, serious and permanent bodily injury to the Plaintiff arising from or related to the sale and use in this State of an unreasonably dangerous and defective product causing injury.

65. At all times relevant to this action, EES has conducted substantial business in Vermont and regularly caused its products to be sold in Vermont, including the product at issue.

66. EES is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, Vermont 05633. Service individually and by the Secretary of State should be upon Defendant EES at its principal place of business at 475 Street C Los Frailes Industrial Park, Suite 401, Guaynabo, Puerto Rico 00969.[20]

H. DEFENDANT ETHICON US, LLC.

67. Defendant ETHICON US, LLC (hereinafter "ETH US") is a limited liability corporation organized under the laws of Texas with a principal place of business in New Jersey.

[20] *See* FN 11, *supra.*

68. ETH US's principal office is 1125 Bear Tavern Road, Titusville, NJ 08560.

69. ETH US is a subsidiary of Johnson & Johnson.[21] EES is a single member LLC owned 100% by Ethicon Endo-Surgery. In the alternative, EES' sole member is one of the Johnson & Johnson family of companies, or is a combination of the J&J "family" members, and all in the "family" are not citizens/domiciled or headquartered in the forum state of Vermont.

70. ETH US, in coordination with the other Defendants, was in the business of selling medical devices throughout the State of Vermont, including the ILS.

71. ETH US and its employees, in coordination with the other Defendants herein, were involved in the manufacture, distribution, sales, marketing, regulatory management, design, and related services of such medical products in the United States, and specifically the ILS-No. ECS29A alleged to have caused injury here.

72. ETH US is therefore subject to the personal jurisdiction of this Court because of the claims stated in this Complaint allege, to wit, serious and permanent bodily injury to the Plaintiff arising from or related to its sale and use in this State of an unreasonably dangerous and defective product causing injury.

73. ETH US is without an agent for service of process in Vermont and therefore should be served by certified mail and by service of process at the Vermont Secretary of State at 128 State Street, Montpelier, VT 05633. Service individually and by the Secretary of State should be upon Defendant EES at its principal place of business at 1125 Bear Tavern Road, Titusville, NJ 08560.[22]

[21] *See* FN 10, *supra.*
[22] *See* FN 11, *supra.*

I. THE "CORPORATE DEFENDANTS" & PIERCING THEIR CORPORATE VEIL.

74. Defendants Johnson & Johnson, J&J Consumer, J&J Health, Ethicon, Inc., Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery, LLC, and Ethicon US, LLC are hereinafter collectively referred to as "Corporate Defendants" or "Defendants."

75. At all relevant times herein mentioned, the Corporate Defendants participated in the promotion, manufacture, sale, and distribution of the specific ILS-No. ECS29A that is the subject of this case when they knew, or with the exercise of reasonable care should have known, of its increased risks, hazards, and unreasonably dangerous propensities, and thereby actively participated in and coordinated with each other the tortious conduct which resulted in serious injuries to the Plaintiffs.

76. There exists, and at all relevant times herein mentioned, there existed, a unity of interest in ownership and management between Corporate Defendants such that any individuality and separateness between them ceased; thus, the Corporate Defendants are the alter ego of each other, one acting for the other in relation to manufacturing an unreasonably dangerous and defective product.

77. Adherence to the fiction of the separate existence of any Defendant as any entity distinct from other Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

78. At all relevant times herein mentioned, the Corporate Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the ILS-No. ECS29A alleged to have caused injury here.

79. This device was for use by the Plaintiff and Plaintiff's physicians.

80. As such, each of the Corporate Defendants are individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

81. The harm caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information about which one, or which combination caused the injuries.

82. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms shown to be suffered by the Plaintiffs from Defendants' ILS.

III. JURISDICTION & VENUE

83. This Court has subject matter jurisdiction pursuant to 28 USC § 1332(a) as there exists complete diversity of citizenship between the Plaintiff and Defendants and the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interests and costs.

84. Defendants collectively had the power and authority, as well as the obligation, to direct the business operations related to ILS-No. ECS29A in Vermont.

85. Further, pursuant to FRCP 4(k)(1)(A) and 12 V.S.A. § 913(b), this Court has specific personal jurisdiction over the Corporate Defendants. Pursuant to 12 V.S.A. § 913(b), Defendants' activity in the State of Vermont are "sufficient to support a personal judgment against him or her."

86. At all relevant times, the Corporate Defendants collectively transacted, solicited, and conducted business in the State of Vermont through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Vermont by marketing the

ILS-No. ECS29A to the healthcare providers in this State. As a result, Plaintiff's claims arose out of Defendants' conduct that occurred in Vermont coordinated by all Defendants.

87. Jurisdiction in this Court is also proper because the Defendants committed torts in whole or in part against the Plaintiff in this State and contracted to supply the ILS-No. ECS29A used in Plaintiff Griffin's surgery, which was an unreasonably dangerous and defective product and a substantial factor in Plaintiff's injuries.

88. Because Vermont Superior Court would have personal jurisdiction over the Corporate Defendants, FRCP 4(k)(1)(A) establishes that this Court also has personal jurisdiction over the Corporate Defendants.

89. As alleged in paragraphs 74-82, the Corporate Defendants herein are unitary, so that jurisdiction over one of them would provide a basis for specific personal jurisdiction of all.

90. Venue is proper in this Court, pursuant to 28 USC § 1391 (b)(2), because the claims set forth in this Complaint, to wit, serious and permanent bodily injury to the Plaintiff, arising from negligent acts and omissions coordinated collectively among the Defendants, allegedly resulting in Plaintiff's injuries occurred in the County of Rutland, Vermont.

91. Plaintiff's harms and losses directly and proximately caused by the negligent acts and omissions of the Defendants, exceed the minimum dollar amount necessary to establish jurisdiction in this Court.

92. The Defendants herein are all properly joined in this action pursuant to FRCP 20 as the Plaintiff asserts jointly, severally, or in the alternative, a right to relief in respect of or arising out of the same transaction, occurrence, or series of transactions or occurrences and a question of law or fact is common to all Defendants in the action.

IV. FACTS

A. HISTORY OF SURGICAL STAPLERS AND MALFUNCTIONS.

93. Since the early 1900s, surgical staplers have been used in the medical community to assist in a number of medical operations and procedures.[23]

94. Typically, a stapler is comprised "of the stapler body, a staple cartridge/reload with lines of staplers, an anvil, and a firing mechanism. The surgeon loads a staple cartridge into the stapler (unless they are using a preloaded device) before placing the tissue to be connected between the stapler jaws (comprising of the cartridge and anvil). They then activate the firing mechanism to shoot a staple into place."[24]

95. Innovations in the manufacturing of surgical staplers have led to the creation of different categories of staplers to assist with specific procedures.

96. One of these categories is the circular stapler, which is "used in general surgery as well as thoracic surgery, bariatric surgery and colo-rectal surgery. They are designed to enable end-to-end, side-to-end and side-to-side anastomoses and, as the name suggests, place staples in a circular shape consisting of two concentric rings."[25]

97. Surgical staplers, therefore, have been used for decades for a variety of procedures, including to remove a part of an organ (otherwise known as a "resection"), to cut through tissue and organs ("transection"), and to create connections between structures in the body ("anastomoses").[26]

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[23] *See* Sophie Childs, *Everything Healthcare Professionals Need to Know about Surgical Staples*, CIA (Apr. 18, 2017), https://web.archive.org/web/20201112010442/https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about-surgical-staples//.

[24] *Id.*

[25] *Id.*

[26] *Surgical Staplers and Staples*, attached as Exhibit 6.

98. The FDA has acknowledged that the advantages of using surgical staples and staplers include: "Quick placement; Minimal tissue reaction; Low risk of infection; [and] Strong wound closure."[27]

99. Despite their many uses and history of development in the medical community, surgical staplers also have a long history of malfunctions since their creation and use in a variety of surgical operations. For example, by 2004, studies had shown that 112 deaths, 2,180 injuries, and 22,804 adverse events ("AEs") reported to the FDA were associated with surgical staplers.[28]

100. In fact, one survey found that the incidence rate of stapler malfunction is so high that "86% of laparoscopic surgeons either had personal experience with or knew of surgeons who experienced stapler malfunction."[29]

101. Other studies have found that, on average, 8-9,000 AEs related to surgical staplers occur per year, with 90% of these AEs resulting from a malfunction with the device.[30]

102. Further, the possible consequences of a malfunction can be very serious, as the FDA explained, "[i]n a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions." Likewise, "[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence."[31]

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[27] *Id.*
[28] *See* S. Lori Brown, *Surgical stapler-associated fatalities and adverse events reported to the Food and Drug Administration*, JACS (May 2004), available at https://www.journalacs.org/article/S1072-7515(04)00754-9/abstract.
[29] Samwel Okoth Makanyengo and Dhan Thiruchelvam, *Literature Review on the Incidence of Primary Stapler Malfunction*, 27 SURG. INNOV., 229-34 (Apr. 2020).
[30] *Everything Healthcare Professionals Need to Know*, *supra* FN 23.
[31] *FDA Executive Summary*, attached as Exhibit 7 at 11.

103. Even if the malfunction does not cause a potentially fatal injury for the patient, such "complications frequently require additional diagnostic studies, invasive procedures and in the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care."[32]

104. As a result of these complications and the ubiquitous malfunctions that have plagued surgical staplers for years, the FDA conducted a review of the studies that have been used to investigate these issues.[33]

105. By examining these studies, the FDA concluded that the most commonly reported malfunctions associated with surgical staplers include malformed staples, missing staples, stapler jamming, and misfires.[34]

106. By 2013, Defendants and the medical device industry in general should have been aware that malfunctioning surgical staplers generally presented serious risks of injuries during surgery and that the true risk of injury was unknown and unexamined. Despite this obvious problem, these Defendants took no steps to measure the true risks of these devices.

107. One medical article concluded "[m]ost minimally invasive surgeons have experienced laparoscopic linear stapler malfunction and 25% have had to significantly alter the planned operative procedure due to the malfunction." [35] Further:

> Our surgeons recently experienced several independent adverse events involving the laparoscopic linear stapler. Although the Food and Drug Administration maintains a Manufacturer and User Facility Device Experience (MAUDE) database to track such voluntary reports, many events are not reported, and the true incidence of adverse events is unknown.[36]

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[32] *Id.* at 9.
[33] *Id.* at 10.
[34] *Id.* at 10-11. Of these malfunctions, malformed staples were the most commonly reported malfunction, comprising 31.8% of all reported malfunctions identified in the studies examined by the FDA. *See id.* at 10.
[35] D R Kwazneski, et al., *The Unacknowledged Incidence of Laparoscopic Stapler Malfunction*, 27 SURG ENDOSC 86-9 (Jan. 2013), https://pubmed.ncbi.nlm.nih.gov/22806510/.
[36] *Id.*

108. Part of the problem was the method by which manufacturers chose to track and report AEs relating to their products.

109. The FDA allowed makers of these staplers to make summary reports of AEs into the FDA Maude database.[37]

110. These "Summary Reports" allowed manufacturers to conceal injuries related to these devices from public scrutiny.[38]

111. Overall, Defendants at all relevant times were or should have been aware of the dangers a defective surgical stapler posed for the general public and should have and were expected to maintain effective procedures to properly manufacture the ILS and appropriately respond when the ILS was found to be defective. Unfortunately, this is not the case.

B. DESCRIPTION OF THE ILS.

112. The ILS was, at the time of manufacture, a Class II medical device.[39]

113. Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA Regulations, Defendant Ethicon Endo-Surgery submitted a premarket notification submission pursuant to the 510(k) Classification Process to sell the ILS on the open interstate market.[40]

114. Under Section 510(k) of the FDCA, a device can be introduced into interstate commerce if the FDA determines that the proposed device is substantially equivalent ("SE") to an already approved predicate device.[41]

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[37] Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, KHN (Mar. 7, 2019), https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/.
[38] *Id.*
[39] *Safe use*, *supra* note 7.
[40] For more information on the 510(k)-classification process, *see The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, attached as Exhibit 8.
[41] *Id.* at 3.

115. In other words, "[a] 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act)."[42]

116. This process is different from the Premarket Approval ("PMA") standard because "[t]he 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness."[43]

117. As part of this comparative process, the FDA must determine that the proposed device's and the predicate device's uses are "the same" and that "the two devices have 'the same technological characteristics,' or that a 'significant change in the materials, design, energy source or other features of the device' does not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device."[44]

118. Put another way:

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;

or

- has the same intended use as the predicate; **and**
- has different technological characteristics and does not raise different questions of safety and effectiveness; **and**
- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.[45]

119. Once a device has been determined to be SE to a predicate device, "the new device is classified into the same class and subject to the same requirements as the predicate device."[46]

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[42] *Premarket Notification 510(k)*, attached as Exhibit 9.
[43] *Id.* at 6.
[44] *Id.*
[45] *Premarket Notification*, FN 42, *supra.*
[46] *Id.* at 3.

120. "Thus, 510(k) review is both the mechanism by which a manufacturer seeks marketing authorization for a new device and by which FDA classifies devices into their appropriate regulatory category."[47]

121. Here, Defendant Ethicon Endo-Surgery filed its 510(k) premarket notifications for the ILS in 1994 and 1998, both of which were found to be SE.[48]

122. On May 27, 1994, Ethicon Endo-Surgery was cleared by order of the FDA[49] to market an "Endoscopic Tissue Approximation Device,"[50] based on a showing that the device was "substantially equivalent" or "SE" to other similar devices already on the market.

123. On December 18, 1998, Ethicon Endo-Surgery was issued by the FDA an "order" or letter releasing to market the "Proximate Curved and Straight Intraluminal Staplers,"[51] based on a showing that the device was "substantially equivalent" or "SE" to other similar devices already on the market.

124. The 510(k)-notification required to be submitted relating to 510(k) Numbers K940967 and K983536 for these devices is generally described by the FDA as follows:

> Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval application (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) ....
>
> Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and

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[47] *Id.*

[48] *See* Modified Endopath ILS 510(k) Premarket Notification and Proximate Curved and Straight Intraluminal Staplers 510(k) Premarket Notification, attached as Exhibit 10 and 11 respectively.

[49] "The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation." Quoting *What We Do*, attached as Exhibit 12.

[50] *See* FN 48, *supra*, Exhibit 10.

[51] *See* FN 48, *supra*, Exhibit 11.

> states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution (see The 510(k) Program Guidance).[52]

125. The Endoscopic Curved Intraluminal Stapler, 29 mm diameter, No. ECS29A, which is the product at issue in this case, was marketed pursuant to a letter, attached hereto as Exhibit 13, dated December 18, 1998.

126. The letter allowed Ethicon Endo-Surgery to market the "PROXIMATE® Curved and Straight Intraluminal Staplers" subject generally to FDA regulations.

127. The letter (or FDA "Order"), which was sent to Edwin O. Billips, Senior Associate Regulatory Affairs for Ethicon Endo-Surgery at its Ohio headquarters, stated:

> You may, therefore, market the device, subject to the general controls provisions of the [FDCA]. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

128. The letter (order, attached Exhibit 13) cleared Ethicon Endo-Surgery to market the ILS in compliance with FDA and its "general controls" applicable to all such devices, and its Regulations, as follows:

> Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

129. The FDA's clearance for marketing of such devices was conditional on Defendant Ethicon Endo-Surgery executing its non-delegable duties to abide by the FDA's general controls and regulations, including maintaining CGMPs and to "establish and follow quality systems to

[52] *Premarket Notification*, *supra* FN 42.

help ensure that their products consistently meet applicable requirements and specifications."[53]

130. The ILS were and are marketed as a sterile, single-patient use device that "has application throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomosis."[54]

131. The ILS uses controlled tissue compression and adjustable height staples "to allow the surgeon to deliver the appropriate compression for each patient based on their experience and expertise."[55]

132. "Through adjustable height staples, the Ethicon Endo-Surgery ILS accommodates compressed tissue thicknesses anywhere between 1.0 and 2.5 millimeters."[56]

133. Further, "[a]djustable height staples with a 5.5-millimeter open leg length are formed to the appropriate closed height based on the amount of compression applied to the tissue… [A]llowing a tailored solution in one device for each unique patient."[57]

134. "After the ILS is fired and removed from the anastomosis, the closed staples continue to provide the required tissue compression throughout the healing process."[58]

135. The ILS-No. ECS29A, along with other circular staplers, was marketed as having "true audible and tactile feedback as the surgeon completes the firing sequence."[59]

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[53] *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, attached as Exhibit 14.
[54] *See* Ethicon, *Intraluminal Circular Stapler – Device Assembly*, YOUTUBE (July 17, 2015), https://www.youtube.com/watch?v=uAxYglshHQ4&list=PLKz9xVMv1rQccXNeD89RUJ1KxzwgVkg15&index=9&t=0s; *see also* Exhibit 1.
[55] Ethicon, *Intraluminal Circular Stapler – Advantage of Adjustable Height Staples in Intraluminal Circular Stapler*, YOUTUBE (July 4, 2016), https://www.youtube.com/watch?v=snlnLnY1_GY&list=PLKz9xVMv1rQccXNeD89RUJ1KxzwgVkg15&index=2&t=0s.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] Ethicon, *Intraluminal Circular Stapler – Tactile and Audible Feedback in Intraluminal Circular Stapler*, YOUTUBE (August 1, 2015), https://www.youtube.com/watch?v=mDmKffhvsFw&list=PLKz9xVMv1rQccXNeD89RUJ1KxzwgVkg15&index=7; *see also* Exhibit 1.

136. During the firing sequence, "the knife cuts through the tissue first and then the breakaway washer, providing distinct audible and tactile feedback to the surgeon."[60]

137. As the FDA has explained, "[w]hen the washer is cut, confirming completion of the firing cycle, the surgeon experiences an audible and tactile crunch."[61]

C. MANUFACTURING SHIFT AND RECALL.

138. 21 CFR 820.70 requires: "Each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications." Although the ILS-No. ECS29A was designed to specifications to perform as described in ¶¶123 to 130 above, in or around March of 2018, a shift in the manufacturing of the ILS-No. ECS29A occurred causing deviations in those device specifications.

139. As a result of this shift, Ethicon's ILS manufactured from March of 2018 to March 6, 2019 (when the manufacturing line was shut down) were unable to sufficiently fire the washers, causing uncut washers and malformed staples in the ILS that compromised the staple line integrity in the patient's anastomosis.

140. During this time, 92,496 ILS were sold throughout the United States with such deviations in specifications.[62]

141. As the FDA explained in their recall notice, "[f]ailure to cut the washer suggests complete 360-degree staple line failure."[63]

142. If a staple line failure occurs, the patient may experience a number of injuries, including but not limited to: "death, sepsis, bleeding, the need for permanent ostomy 'bag,' life-long nutritional and digestive issues, leak in the closure (anastomotic leak), additional surgeries,

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[60] *Id.*
[61] *Ethicon Recalls Circular Staplers*, attached as Exhibit 2.
[62] *Id.*
[63] *Id.*

need for additional closures (anastomoses), need for antibiotics, and the need for additional imaging studies."[64]

143. As previously explained, Defendants have long known of the risks of serious injury and death associated with its surgical staplers like the one used on Plaintiff. Between January 2011-March 2018, over 41,000 adverse events were reported with these devices—including over 360 deaths.[65]

144. As a result of these risks, medical device manufacturers like Defendants must establish and follow Quality Systems ("QS") to help ensure that their products are manufactured as intended for use, can safely be used in patient surgical procedures and will not deviate from their intended specifications. QS for FDA-regulated products, including medical devices, are known as Current Good Manufacturing Practices ("CGMP's").[66]

145. Class II medical devices, like the ILS when it was manufactured, are not as heavily regulated or monitored like Class III medical devices.[67]

146. As a result, the ILS-No. ECS29A did not require premarket approval from the FDA.[68]

147. However, as explained in the FDA letter granting Defendant Ethicon Endo-Surgery authorization to market the ILS, Defendants were required to adhere to the general control provisions of the FDCA, including "requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration."[69]

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[64] *Id.*
[65] *Safe use*, attached as Exhibit 3.
[66] *See* 21 CFR 820.
[67] *See Safe use*, attached as Exhibit 3.
[68] *Id.*
[69] *See* Exhibit 11.

148. Despite these requirements and the potential for serious injury, Defendants failed to maintain QS and CGMP's to ensure that the ILS-No. ECS29A would not deviate from specifications, thus causing manufacturing defects exposing patients to risks of serious injury or death when used as intended by the surgeon.

149. These Corporate Defendants knew, and/or had reason to know, that the ILS was defective and unreasonably dangerous.

150. Defendants' failure to establish effective PMSS, AE complaint reporting, and investigation units allowed a serious manufacturing defect to continue and go unreported for over a year after the defective lots of the ILS were released to the U.S. public.

151. Any patients who underwent a medical procedure with one of Ethicon's ILS manufactured from March 6, 2018 to March 6, 2019 were exposed to a serious risk of death or severe injuries.

152. On or around April 11, 2019, EES, in coordination with the other Defendants, issued a voluntary recall of the ILS's with the following product numbers: CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, **ECS29A**, and ECS33A.[70]

153. Per this recall, Defendants "confirmed the occurrence of uncut washers and malformed staples with our [ILS] which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognized, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, hemorrhage, or hemorrhagic shock."[71]

[70] *See* Exhibit 4, Ethicon Recall Letter (emphasis added).
[71] *Id.*

D. FDA RESPONSE TO ETHICON RECALL AND SURGICAL STAPLER MALFUNCTIONS.

154. Shortly after Ethicon's recall, on or around April 23, 2019, the FDA issued a Draft Guidance letter for labeling recommendations for surgical staples and staplers.[72]

155. On or around May 15, 2019, the FDA followed up on Ethicon's recall by issuing a Class I Recall of the ILS themselves, listing a total of 10 devices subject to a Class I Recall.[73]

156. As stated in ¶20 above, Ethicon Endo-Surgery was listed as the "Recall/Manufacturer" for each of these 10 devices.

157. A Class I Recall is considered the most serious classification of recall and is used in "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[74]

158. During the same time period, on March 8, 2019, the FDA issued a letter to healthcare providers highlighting the risks and problems related to surgical staplers generally.[75]

159. By April of 2019, the FDA announced its intent to reclassify surgical staplers from low risk to a stricter approval process.[76]

160. The FDA explained that it intended to "to reclassify surgical staplers for internal use from class I (general controls), exempt from premarket review, to class II (special controls), subject to premarket review. FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance."[77]

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[72] *Surgical Staplers and Staples for Internal Use - Labeling Recommendations*, attached as Exhibit 15.
[73] *See FDA Spreadsheet of Recalled Staplers*, attached as Exhibit 5.
[74] *Recalls, Corrections and Removals (Devices)*, attached as Exhibit 16.
[75] *Safe Use*, attached as Exhibit 3.
[76] *General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers*, attached as Exhibit 17.
[77] *Id.*

161. The FDA reasoned that this reclassification was necessary, in part, due to complications that can result from surgical stapler malfunctions, which could result in "prolonged surgical procedures, unplanned surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death."[78]

162. The FDA also illustrated the high rate of reported incidents, also known as Medical Device Reports ("MDRs"), associated with surgical staplers. The FDA summarized its findings by explaining that:

> From January 1, 2011, to March 31, 2018, FDA received over 41,000 individual MDRs for surgical staplers and staples for internal use, including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. Some of the most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to tissue).[79]

163. It was also noted that "[t]he most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty of opening/closing the stapler, stapler misfiring, and stapler breakage. The most commonly reported patient consequences from malfunctions with surgical staplers for internal use included a delay in surgical procedure, hemorrhage, and tissue damage."[80]

164. Beyond these findings, however, the FDA also reported that "[f]rom November 1, 2002, to December 30, 2018, FDA received a total of 168 recalls for surgical staplers and staples for internal use under product codes GAG and GDW, including one class I recall and 167 class II recalls."[81] "Of the 167 class II recalls, the most common reasons for recall included non-

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[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *Id.*

conforming device components or device design-related issues that may result in incomplete staple formation, failure to form a staple line, malformed staples, or difficulty in firing."[82]

165. As a result of these data and findings, on or around April 24, 2019, the FDA issued a proposed order to allow for this reclassification.[83]

166. This proposed reclassification would include, among other requirements, adequate performance testing to mitigate the risk of device malfunction and would "include an evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type; measurement of the worst-case deployment pressures on stapler firing force; and a measurement of staple line strength."[84]

167. That same day, the FDA also issued a draft guidance document to assist with the labeling of surgical staplers.[85] The FDA explained that "[b]oth device misuse and device malfunctions are root causes of these adverse events. FDA believes that these problems may be mitigated by providing specific information about the risks, limitations, and directions for use in the labeling for the surgical staplers and staples for internal use."[86]

168. Because of the risks associated with surgical staples, including Ethicon's ILS, the FDA held a public meeting on or around May 30-31, 2019 to discuss whether surgical staplers should be reclassified as a Class II medical device, which would require manufacturers to give "premarket notification and allow the FDA to establish mandatory special controls to help mitigate known risks of the device."[87]

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[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Surgical Staplers and Staples for Internal Use-Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability,* attached as Exhibit 18.
[86] *Id.*
[87] *General and Plastic Surgery Devices Advisory Committee Meeting*, attached as Exhibit 19.

169. At the conclusion of the meeting, the FDA panel "unanimously recommended the reclassification of surgical staplers for internal use from Class I (general controls) to Class II (special controls).[88]

V. GENERAL ALLEGATIONS

170. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

171. At all relevant times, the ILS was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by the Corporate Defendants.

172. Corporate Defendants negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold labelled, and distributed the ILS as a safe and effective device to be used for surgical procedures.

173. Corporate Defendants knew, and/or had reason to know, that the ILS was defective, unreasonably dangerous, and not safe because of AEs that the Corporate Defendants knew about.

Representations

174. Corporate Defendants negligently, carelessly, recklessly, and/or intentionally promoted the ILS to physicians and patients, including the Plaintiff David Griffin and his physicians.

175. Corporate Defendants misrepresented the safety of the ILS to physicians and patients, including Plaintiff David Griffin and his physicians.

176. Corporate Defendants willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiff David Griffin and his physicians, of the increased risks

[88] *Id.*

and significant dangers resulting from being operated on with the ILS.

177. Corporate Defendants knew and/or had reason to know, that their representations and suggestions to physicians that the ILS was safe were materially false and misleading such that physicians and patients, including Plaintiff David Griffin and his physicians, would rely on such representations.

178. Any warnings Corporate Defendants may have issued concerning the risks and dangers of the ILS were inadequate and insufficient considering the shift in manufacturing and defect that existed in the ILS.

179. Corporate Defendants knew and/or had reason to know of the likelihood of serious injuries caused by the promotion, sale, and distribution of the ILS, but they failed to establish an adequate quality control system and complaint systems to monitor and evaluate the ILS and thus prevented Plaintiff David Griffin and his physicians from being aware of the heightened risk of using the ILS before it was too late.

Causation

180. Plaintiff David Griffin would not have consented to undergo his procedure with the use of the ILS had Plaintiff David Griffin known or been fully and adequately informed by Corporate Defendants of the true increased risks, hazards, and serious dangers of the ILS.

181. Plaintiff David Griffin and his physicians reasonably relied on Defendants' representations and omissions regarding the safety and efficacy of the ILS.

182. Plaintiff David Griffin and his physicians did not know of the specific increased risks and serious dangers, and/or were misled by Corporate Defendants, who knew or should have known of the true risks and dangers.

183. Corporate Defendants' promotion and marketing of the ILS caused Plaintiff David Griffin's physicians to decide to use the ILS during his operation. Plaintiff David Griffin's physicians would not have recommended and used the ILS in the absence of Corporate Defendants' false and misleading promotion.

Damages

184. Plaintiff has suffered serious personal injuries as a direct and proximate result of Corporate Defendants' misconduct.

185. As a direct and proximate result of Corporate Defendants' conduct, Plaintiff David Griffin has suffered and will continue to suffer from severe injuries and damages, including but not limited to abdominal pain, hemorrhaging, and subsequent surgeries to repair the damage caused by the ILS.

186. As a result of Corporate Defendants' failure to adequately warn of the risks and dangers associated with the ILS as manufactured, promoted, sold and supplied by these companies, and as a result of the negligence and other wrongdoing and misconduct of Corporate Defendants as described herein:

a. Plaintiff David Griffin has been injured and suffered and will continue to suffer injuries to their body and mind, the exact nature of which are not completely known to date.

b. Plaintiff David Griffin has sustained and will continue to sustain economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown.

c. Plaintiff David Griffin has incurred and will be required to incur additional medical expenses in the future to care for themselves as a result of the injuries and damages Plaintiff has suffered; and

d. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

187. Plaintiff herein brings his causes of action within the applicable statute of limitation. Specifically, Plaintiff brings his action within the prescribed time limits following their injuries and their knowledge of the wrongful cause. Prior to such time, Plaintiff did not know nor had reason to know of his injuries and/or the wrongful cause thereof.

188. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

VI. PLAINTIFF'S ALLEGATIONS

189. Plaintiff David Griffin is fifty-two (52) years old and resides in Proctor, Rutland County, Vermont.

A. Initial Procedure with ILS:

190. On or around August 13, 2018, Plaintiff presented to Rutland Regional Medical Center ("Rutland") in Rutland County, Vermont, with complaints of severe abdominal pain. That same day, he underwent a CT scan of his abdomen and pelvis, which was conducted by Dr. Talitha Travis. Both Dr. Travis and the Emergency Room ("ER") physician, Dr. Christopher Stronczak, diagnosed Plaintiff with Acute Sigmoid Diverticulitis with an abscess.

191. As a result of this diagnosis, Plaintiff was treated with a ten-day course of antibiotics. This treatment appeared to resolve Plaintiff's symptoms, but two weeks later Plaintiff suffered another diverticular attack and was put on antibiotics again.

192. On or around September 10, 2018, Plaintiff met with Dr. Matthew Conway at Rutland General Surgery, who suggested Plaintiff undergo a laparoscopic assisted sigmoid colectomy to treat his diverticulitis.

193. A sigmoid colectomy is a procedure that results in the removal of the sigmoid colon specifically and the ends of the remaining portions of the patient's bowels, specifically the

descending colon and rectum, are joined by stitching or stapling them together through a process called anastomosis.[89] The procedure is considered to be a "reliable, safe, and efficacious treatment modality for chronic diverticular disease."[90]

194. On or around September 15, 2018, Plaintiff underwent an attempted laparoscopic-assisted sigmoid colectomy which was conducted by Dr. Conway at Rutland. A stapler, later identified as an Ethicon ECS29A stapler, was used during the operation.

195. Unfortunately, during the procedure, Dr. Conway notes in the operative report that when the stapler fired, "**it appears not to have completed its staple line at its initial attempts to fire the stapler. Reattempted firing of the stapler was successful, but there was noted hemorrhage and ultimately failure of that staple line as a consequence of the, I believe trauma and difficulty of the first firing.**" (emphasis added).

196. Due to this failure of the stapler, Dr. Conway was forced to convert the procedure from a laparoscopic-assisted sigmoid colectomy to an open low anterior resection.

197. A lower anterior resection is a procedure in which a diseased portion of the rectum and sigmoid colon is removed, and an anastomosis (a surgical joining of tubular structures) is created by an endoscopic stapler or similar device by attaching the colon to the remaining portion of the rectum. This is done to ensure the patient's fecal matter can be expelled from the body properly.[91]

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[89] For a more detailed explanation of a Sigmoid Colectomy, *see* Paul Litchfield & Maddie White, *Sigmoid Colectomy – Your operation explained*, UNIVERSITY HOSPITALS BIRMINGHAM (May 2019), https://www.uhb.nhs.uk/Downloads/pdf/PiSigmoidColectomy.pdf.

[90] Mark Blake, et al., *Laparoscopic Sigmoid Colectomy for Chronic Diverticular Disease*, JSLS (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3015646/.

[91] For a more detailed explanation of a Low Anterior Resection, *see Types of colorectal cancer resection surgeries*, COLORECTAL CANCER ALLIANCE (Feb. 4, 2019), https://www.ccalliance.org/blog/patient-support/types-of-colorectal-cancer-resection-surgeries; *Surgery for Rectal Cancer*, AMERICAN CANCER SOCIETY, http://www.cancer.org/cancer/colon-rectal-cancer/treating/rectal-surgery.html (last accessed Feb. 13, 2019).

198. Due to this complication, Plaintiff lost over two liters of blood during the operation and, per the pathology report, was forced to have removed portions of both his sigmoid colon and rectum.

199. Due to the loss of blood, Plaintiff became hypotensive and Dr. Conway ended the procedure by oversewing Plaintiff's rectum and conducting a proximal colostomy in stabilize his condition, with plans to reverse the procedure in a few months.

200. After the operation was concluded, Plaintiff was kept at Rutland for a few more days for observation and treatment, during which Plaintiff was noted to have continuing abdominal pain. On or around September 19, 2018, Plaintiff was discharged from Rutland.

B. Post Procedure Condition and Treatment:

201. Plaintiff Griffin's post-procedure course has been marked by abdominal pain, fatigue.

202. On or around October 16, 2018, Plaintiff met with Dr. Conway for a follow-up. Plaintiff reported that his strength and energy were still not perfect and that he had not been able to return to work. Plaintiff also reported that he still experienced some abdominal pain, but that it was minimal and that his strength and energy were improving. Dr. Conway gave Plaintiff a note allowing him to go back to work and planned to meet with Plaintiff in approximately a month to discuss plans to reverse his colostomy.

203. On or around November 13, 2018, Plaintiff met with Dr. Conway again and reported that he was feeling well. Dr. Conway discussed the procedure to reverse the colostomy and both agreed to try and schedule the reversal for some time in the third week of December.

204. On or around December 19, 2018, Plaintiff underwent a rigid proctosigmoidoscopy and colostomy takedown with primary re-anastomosis and a small segmental resection of the colon at the colostomy site. Dr. Conway conducted the procedures.

205. Dr. Conway notes in the operative report that there was a fair bit of intraabdominal scarring "necessitating a lysis of adhesions," but the tissue appeared to be healthy otherwise.

206. Plaintiff stayed at Rutland for several days after the colostomy removal for observation and continued treatment. Plaintiff recovered well from the procedure and on or around December 24, 2018, Plaintiff was discharged from Rutland with plans to follow up with General Surgery in a week for staple removal.

207. On or around January 2, 2019, Plaintiff met with Dr. Conway again to have his staples removed. Plaintiff mentioned during the visit that he was having some issues with pain and that he was not yet ready to return to work.

208. On or around January 11, 2019, Plaintiff had a follow-up with Physician Assistant Blake Lopes. During the follow-up, Plaintiff stated that he was feeling better, but was continuing to experience cramping and abdominal pain and that he was continuing to feel fatigued. Plaintiff also stated he did not feel ready to go back to work.

209. On or around January 17, 2019, Plaintiff returned for another follow-up with PA Lopes. Plaintiff stated his abdominal pain was nearly resolved and that he was taking more walks to help with his fatigue. He also stated he felt he was ready to return to work on the 21st.

210. On or around April 11, 2019, Rutland received the Recall Letter from Ethicon, attached as Exhibit 4, stating that certain Ethicon stapler models, including the one used during Plaintiff's operation, were being recalled by the manufacturer.

211. On or around May 22, 2019, Plaintiff met with Dr. Conway to report that he was feeling better than he had for the past year. Dr. Conway reported that Plaintiff "had a long difficult course, but thankfully at this point, he seems healed," and that Plaintiff could follow-up as needed.

212. Despite this improvement, Plaintiff has suffered from permanent and debilitating injuries that will affect him for the rest of his life. Plaintiff was forced to have more of his colon removed than was originally planned due to the stapler failure that occurred during his initial operation. Further, Plaintiff was forced to spend extended time at Rutland Regional Medical Center ~~Rutland~~, had to undergo subsequent procedures, and take additional time off work to fully recover from his initial procedure. Plaintiff continues to suffer from abdominal pain and will likely continue to suffer from this pain for the foreseeable future.

VII. AGENCY, ALTER-EGO, JOINT VENTURE, AND CONSPIRACY

213. At all times herein mentioned, the Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of the Defendants repudiated those actions.

214. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

215. There existed (and still exists), during the relevant time periods, a unity of interest between the Defendants such that any individuality and separateness between them has ceased. All these Defendants are the alter-egos of the other Defendant(s) and exerted control over such.

216. Adherence to the fiction of the separate existence of these Defendants, as entities distinct from one another, will permit an abuse of the corporate privilege, sanction a fraud, and promote injustice.

217. Each of the Corporate Defendants herein expressly or impliedly agreed to work with and assist each other Defendants and unnamed parties, toward the common purpose of promoting, recommending, and selling the ILS and toward the common interest of pecuniary gain.

218. Specifically, as previously stated, each of the Corporate Defendants were involved in the manufacture, distribution, and marketing of the ILS at issues in this case.

219. Defendant Ethicon Endo-Surgery was the entity primarily in contact with the FDA during the 510(k) process to introduce the ILS to the general market.[92]

220. Likewise, the FDA identified Defendant Ethicon Endo-Surgery as the "Recalling Firm/Manufacturer" in its Class 1 Recall Notice of the ILS.[93]

221. Defendant EES was also involved in the manufacture and recall of the ILS.

222. Further, although Ethicon Endo-Surgery was ultimately authorized by the FDA to market the ILS and draft and distribute the Instructions for Use ("IFU") and marketing material related to the ILS, ETH US may have done so as Ethicon Endo-Surgery's agent.

223. Defendant Ethicon has been directing the activities of Ethicon Endo-Surgery, including its manufacture of the ILS, its dealings with the FDA, and the recall of the ILS. While Ethicon Endo-Surgery has been the corporate face of the ILS, such actions would not have been possible without Defendant Ethicon's permission and oversight.[94]

224. Finally, as previously stated, Johnson & Johnson is the parent corporation for each of the other Corporate Defendants.[95] Therefore, any actions involving the manufacture,

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[92] *See* Exhibits 10 and 11.
[93] *See Class 1 Device Recall Endoscopic Curved Intraluminal Stapler, 29 mm diameter, Model ECS29A*, ("*Class 1 Device Recall*") attached as Exhibit 20.
[94] *See* Matthew Arnold, *J&J consolidates, rebrands Ethicon units*, ASHFIELD HEALTH (May 8, 2013), https://www.mmm-online.com/home/channel/jj-consolidates-rebrands-ethicon-units/.
[95] *Subsidiaries*, *supra*, FN 10.

distribution, and recall of the ILS could not have occurred without Johnson & Johnson's permission and guidance.

225. Clearly, a complex business structure was developed between each of these Corporate Defendants to facilitate the manufacture, marketing, and distribution of the ILS and each Defendant had its own role in the act of introducing the ILS to the general public.

226. As explained in the FDA letter granting Ethicon Endo-Surgery authorization to market according to ILS, the Corporate Defendants were required to adhere to the general control provisions of the FDCA, including "requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration."[96]

227. The Corporate Defendants' failure to enact these requirements caused the ILS to become defective and to be introduced to the general public and therein led to Plaintiff's injuries.

228. Each of the Corporate Defendants herein performed the acts and omissions described herein in concert with the other Defendants herein and/or pursuant to a common design with the other Defendants herein.

229. Each of the Corporate Defendants herein knew the acts and omissions of the other Corporate Defendants herein constituted a breach of duty, and yet, each Corporate Defendant provided each other Corporate Defendant substantial assistance and/or encouragement.

230. Each of the Corporate Defendants herein provided substantial assistance to the other Corporate Defendants herein in accomplishing the intentional and tortious conduct described herein, and each Corporate Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

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[96] *See* Exhibit 13.

231. At all times herein mentioned, each of the Corporate Defendants were engaged in the business of and/or were a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling the ILS device for use by Plaintiff David Griffin and his physicians. As such, each of the Corporate Defendants are individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

232. The conduct of the Defendants herein caused the Plaintiff's harm as described herein. The Plaintiff's harm is not in any way attributable to any fault of the Plaintiffs. Uncertainty may exist regarding which Corporate Defendant(s) and/or combination of Corporate Defendants caused the Plaintiff's harm. The Corporate Defendants possess superior knowledge and information regarding which Corporate Defendant(s) and/or combination of Corporate Defendants caused the Plaintiff's injuries.

233. Thus, the burden of proof should be upon each Corporate Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiff.

234. Due to the above, each Cause of Action named below is asserted against each Corporate Defendant herein, jointly and severally, even if each and every Corporate Defendant herein is not specifically identified as to each and every count.

VIII. PLAINTIFF IS ENTITLED TO PUNITIVE DAMAGES

235. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

236. The acts and/or omissions of Defendants were grossly negligent, reckless, wanton, and/or willful, thus making Defendants liable to the Plaintiff for punitive damages in order to deter such conduct in the future.

237. Plaintiff seeks an amount in punitive damages that is fair and reasonable as shown by the evidence.

IX. CLAIMS FOR RELIEF

1st CAUSE OF ACTION
Strict Products Liability Manufacturing Defect

238. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

239. The Vermont Supreme Court has adopted the doctrine of "strict product liability" embodied in Restatement (Second) of Torts § 402A.[97]

240. Pursuant to the Restatement (Second) of Torts § 402A:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[97] *See Zaleskie v. Joyce*, 333 A.2d 110, 113 (Vt. 1975); *see also Moffitt v. Icynene*, Inc., 407 F. Supp. 2d 591, 599 (D. Vt. 2005).

241. A product is defective if it is not "safe for normal handling and consumption."'[98]

242. Stated differently, "[a] defective product "must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."'[99]

243. While the plaintiff bears the burden of proving the device was defective and that the defect was the cause of plaintiff's injuries, the plaintiff "is relieved of showing that the defendant was negligent."[100]

244. Although the Defendants knew or should have known of the inherent dangerousness of the product at the time it was manufactured, Defendants in this case failed in their duty to apprise Plaintiff's healthcare providers of the "dangerous propensities" of the Ethicon's ILS-No. ECS29A at the time it was used by Plaintiff's surgeon.

245. At the time the Ethicon's ILS-No. ECS29A was distributed to Plaintiff's healthcare providers, "the apparent benefits of the [device] exceed[ed] the apparent risks, given the scientific knowledge available when the drug was marketed."

246. At the time the Ethicon's ILS-No. ECS29A was distributed to Plaintiff's healthcare providers, it was manufactured in "noncompliance with [] applicable product safety statute(s) or administrative regulation(s)" imposed by the FDA as set out ¶¶ 123 to 130 above.

247. Plaintiff's physician and his healthcare providers at Rutland selected the ILS-No. ECS29A, using it in Plaintiff's surgery for the specifications as intended by its original design.

248. The Corporate Defendants designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labelled, and sold Ethicon's ILS-No. ECS29A for use in Plaintiff

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[98] *Farnham v. Bombardier, Inc.*, 640 A.2d 47, 48 (Vt. 1994).
[99] *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 346 (Vt. 1996) (citation omitted).
[100] *Id.* (citing *Kinney v. Goodyear Tire & Rubber Co.*, 367 A.2d 677, 679 (Vt. 1976)).

David Griffin's surgery for the purpose (among others) of creating an anastomosis sealed by a staple line created with Ethicon's device.

249. Per Ethicon's voluntary recall letter from April 11, 2019, the Defendants had "confirmed occurrence of uncut washers and malformed staples with [their] Intraluminal Staplers (ILS), which can compromise staple line integrity."[101]

250. These defects were caused by a shift in the manufacturing process for Ethicon's ILS-No. ECS29A that occurred from March of 2018 to March of 2019 when the line was shut down. The FDA confirmed this by issuing a Class 1 Recall of Ethicon's ILS-No. ECS29A on May 15, 2019.[102]

251. At all times material hereto, the Ethicon's ILS-No. ECS29A as designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labelled, and sold by the Corporate Defendants, was expected to reach, and did reach, Plaintiff's physician and his healthcare providers without substantial change to the condition in which it was sold.

252. The Ethicon ILS-No. ECS29A was unreasonably dangerous in its design, manufacturing and/or its warnings when distributed for use because: **(a),** of its inadequate or the non-existent warnings regarding uncut washers and malformed staples likely to occur with its use; **(b),** it was manufactured in noncompliance of general controls and regulations imposed by the FDA; **(c)**, its risks outweighed it benefits when delivered for use; **(d)** it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics; and/or **(e)**, it was manufactured in a manner that resulted in a deviation from its design specifications.

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[101] *See* Exhibit 4.
[102] *See Class 1 Device Recall*, attached as Exhibit 20.

253. Plaintiff Griffin neither knew, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of these unreasonably dangerous defects.

254. Likewise, Plaintiff's physicians and his healthcare providers were not properly informed or warned regarding these issues.

255. Had Plaintiff or his healthcare providers been adequately warned, they would not have used the device and Rutland Regional Medical Center ~~Rutland~~ would not have purchased the device for such use.

256. Had Ethicon's device been manufactured according to FDA regulations and/or according to industry standards, it would not have caused injury to Plaintiff David Griffin.

257. These unreasonably dangerous defects in Ethicon's ILS-No. ECS29A, used in Plaintiff's September 15, 2018 surgical procedure at Rutland Regional Medical Center, were substantial factors in causing Plaintiff David Griffin's severe injuries when the stapler ejected malformed staples and/or an uncut washer—failing to provide an effective anastomosis.

258. As a direct and proximate result of his exposure to Ethicon's ILS-No. ECS29A, Plaintiff David Griffin suffered injuries and therefore asserts claims against Defendants for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost wages, in an amount to be determined by the jury, as well as attorneys' fees, plus costs, and all relief to which Plaintiff is entitled by law.

2nd CAUSE OF ACTION
Negligent Products Liability

259. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further allege as follows:

260. Since the adoption of the strict product liability doctrine, Vermont state and federal courts have clarified that this decision merely expanded, and did not eliminate, Vermont's common law regarding product liability claims.[103]

261. To establish a common law negligence claim against the Corporate Defendants, Plaintiff must demonstrate Corporate Defendants owed him a legal duty, that the Corporate Defendants breached the duty, that the breach of that duty caused his injuries, and that Plaintiff has suffered actual damages.[104]

262. The Corporate Defendants designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labelled, and sold the defective curved intraluminal stapler used on Plaintiff David Griffin.

263. The Corporate Defendants had a duty to exercise reasonable care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, labelled, and sold Ethicon's ILS-No. ECS29A, including a duty to ensure that the stapler did not pose a significantly increased risk of adverse events.

264. These Defendants had a duty to manufacture Ethicon's ILS-No. ECS29A per design specification and to employ QS, CGMP, CAPAs, and PMSS according to general controls and other FDA requirements and regulations to prevent deviations from design specification during manufacturing process, as set in ¶¶ 123 to 130 above.

265. Conformity to these general controls and FDA regulations set out the minimum standard of care expected of a reasonably prudent manufacturer of medical products in the same

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[103] *See Hay v. Med. Ctr. Hosp. of Vt.*, 496 A.2d 939, 945 (Vt. 1985) (stating that the *Zaleskie* case "expanded common law to include strict products liability"); *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 350 (Vt. 1996); *Huey v. Bates*, 375 A.2d 987, 990 (Vt. 1977); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 U.S. Dist. LEXIS 13185, at *10 n.3 (D. Vt. Feb. 3, 2012).

[104] *O'Connell v. Killington, Ltd.*, 665 A.2d 39, 42 (Vt. 1995).

or similar circumstances, providing the medical device industry with a "floor, not a ceiling,"[105] for the standard of care.

266. The Defendants ~~owned~~ owed Plaintiff David Griffin a duty of due care to act as a reasonably prudent medical device manufacturer in the same or similar circumstance in the design, manufacture, inspection, testing, assembly, promotion, distribution, marketing, and labelling of the Ethicon's ILS-No. ECS29A used in Plaintiff's surgery.

267. As measured by industry standards, as well as the minimum standards[106] set out in the controls and the regulations required by the FDA described above, the Defendants breached this duty of due care, and this breach was a substantial factor in causing Plaintiffs' injuries.

268. The breach of the duties of due care, set out above resulted a manufacturing defect, allowing the ejection of malformed staples thus preventing an effective anastomosis during Plaintiff's surgical procedure.

269. Defendants' failure to conform to the standard of care includes but is not limited to the following items:

(a) Failure to establish and maintain effective QS and CGMP's to prevent and/or correct manufacturing deviations from specifications.

(b) Failure to establish and/or maintain a Post Market Safety Surveillance ("PMSS") system and reporting system for Adverse Events ("AE's") for the purpose of

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[105] *Wyeth v. Levine*, 555 U.S. 555, 563 (2009).

[106] A plan to keep a product safe has been a generally recognized duty under common law. *See generally* RESTATEMENT (SECOND) OF TORTS, *§ 395 Negligent Manufacture of Chattel Dangerous Unless Carefully Made*. Comment f to Section 395 explains:

> The particulars in which reasonable care is usually necessary for protection of those whose safety depends upon the character of chattels are (1) the adoption of a **formula or plan which, if properly followed, will produce an article safe for the use** for which it is sold, (2) the **selection of material and parts** to be incorporated in the finished article, … (4) the **making of such inspections and tests during the course of manufacture and *after the article is completed*** as the manufacturer should recognize as reasonably necessary to secure the production of a safe article…(emphasis added).

implementing Corrective and Preventative Actions ("CAPA") to prevent and/or correct deviations in design specifications.

(c) Failure to timely notify purchasers, healthcare professionals, end users, and/or patients of manufacturing deviations associated with their devices; and,

(d) Failure to properly warn users of defects associated with the device when such defects were known or reasonably could have been known at the time of sale.

270. Despite having defective QS, a defective complaint reporting and tracking unit, failing to timely notify relevant parties of a defect associated with its staplers, and failing to provide a proper warning for use of the device, Defendants continued to market the Ethicon ILS as safe and effective for use in patients until the recall notice.

271. The Corporate Defendants waited over a year to act regarding the defect in their staplers, which indicates the Defendants were at the very least grossly negligent and had a reckless disregard for safety in their failure to implement PMSS, CAPAs, effective complaint systems, an adequate AE reporting system, and a QS system for this device to prevent injuries and death to end-users, like Plaintiff.

272. Likewise, the voluntary recall notice and the FDA recall indicate that the device was much more unsafe than had been previously advertised or labelled for users.

273. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost wages, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

274. Further, in doing the acts herein alleged, the Corporate Defendants acted with oppression, fraud, malice and/or deliberate disregard and recklessness toward Plaintiff. Plaintiff is

therefore entitled to compensatory damages and, in addition, to punitive damages to deter Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with advanced knowledge, authorization and/or ratification of an officer, director and/or managing agents of Defendants.

3rd CAUSE OF ACTION
Fraudulent Misrepresentation

275. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

276. Vermont has recognized the following elements for any fraudulent misrepresentation claim: "(1) intentional misrepresentation of a material fact; (2) that was known to be false when made; (3) that was not open to the defrauded party's knowledge; (4) that the defrauded party acts in reliance on that fact; and (5) is thereby harmed."[107]

277. Stated differently, "[f]raudulent misrepresentation can be accomplished affirmatively by false statement or by the concealment of facts by one who has a duty to disclose those facts."[108]

278. The Corporate Defendants owed legal duties to Plaintiff David Griffin to disclose important material facts concerning the safety of the ILS used in his procedure.

279. The Corporate Defendants made material representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the ILS used in his procedure that were false.

280. Specifically, Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that that Ethicon's ILS-No. ECS29A used in Plaintiff's procedure was free of any defects, that Defendants were not aware of any defects associated with that device, and

[107] *In re Estate of Alden v. Dee*, 35 A.3d 950, 960-61 (Vt. 2011) (citing *Lewis v. Cohen*, 603 A.2d 352, 354 (Vt. 1991)).
[108] *Id.* at 961 (citing *Sutfin v. Southworth*, 539 A.2d 986, 988 (Vt. 1987)).

that the stapler was a safe and effective means of performing anastomosis without unexpected complications and injuries.

281. The Corporate Defendants made those false representations to mislead ultimate consumers (like Plaintiff) through misrepresentations of the qualities of the device to Plaintiff's physician or other healthcare providers acting as purchasing agents for Plaintiff. Through their agents, Defendants directly communicated these misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

282. At no time prior to the use of the Corporate Defendants' ILS during Plaintiff's procedure did Defendants acknowledge that the device featured a manufacturing defect, or that it was not safe or effective for its intended use. On the contrary, Defendants intentionally misrepresented through labeling and marketing material that the device was safe and effective for its intended use, and Plaintiff's healthcare providers relied on these false representations in making their decision to use the device in Plaintiff's surgery.

283. The representations made regarding the device to Plaintiff, Plaintiff's physician and/or his healthcare providers or purchasing agents were false because the stapler was ineffective and unsafe for use in any patient due to the manufacturing defect allowing ejection of malformed staples and uncut washers which could not safely render anastomosis.

284. The Corporate Defendants intended the medical professionals at Rutland, including Plaintiff's physicians and his purchasing agents at Rutland, to rely on the Defendants' material misrepresentations regarding the safety of the ILS.

285. Plaintiff and/or his healthcare providers reasonably relied on Defendants' misrepresentations to Plaintiff's detriment. During Plaintiff's procedure, the ILS ejected a malformed staple or uncut washer, causing Plaintiff's severe injuries.

286. As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost wages, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

287. Further, in doing the acts herein alleged, the Corporate Defendants acted with oppression, fraud, malice and/or deliberate disregard and recklessness toward Plaintiffs. Plaintiffs are therefore entitled to compensatory damages and, in addition, to punitive damages to deter Defendants and others from engaging in similar conduct in the future. Said wrongful conduct was done with advanced knowledge, authorization and/or ratification of an officer, director and/or managing agents of Defendants.

4th CAUSE OF ACTION
Strict Liability: Failure to Warn

288. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges as follows:

289. Under Vermont caselaw, "[a] manufacturer also has a duty to warn users and consumers when it knows or has reason to know of dangers inherent in the product at the time the product is sold, Restatement (Second) of Torts § 402A cmt. k, or when the product is dangerous to an extent beyond that which would be contemplated by an ordinary consumer."[109]

290. "To establish strict liability for an inadequate warning, a plaintiff must prove that

[109] *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 347 (1996) (citation omitted).

the inadequate warning made the product unreasonably dangerous and was the proximate cause of the injury."[110]

291. In other words, the plaintiff must prove that the manufacturer or seller had a duty to warn, that the failure to warn made the product unreasonably dangerous/defective, and that the lack of warning was a proximate cause of the plaintiff's injuries.[111]

292. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture, and was so at the time it was distributed by Defendants and implanted into Plaintiff.

293. Corporate Defendants had a duty to disclose and properly warn consumers and purchasers of the true safety profile of the ILS.

294. The aforesaid product was defective in that it was not properly prepared and/or was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of the ILS, and given the severity of the adverse effects, the warnings given did not accurately reflect the symptoms and severity of the adverse effects.

295. The product was also defective in that the product manufactured and distributed differed from the manufacturer's intended results. These defects caused serious injuries to the user when used in its intended and foreseeable manner.

296. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product, i.e. for use in gastrointestinal operations to create a secure anastomosis within the body, involved substantial dangers not readily recognizable by the ordinary user of the product. The Defendants, and each of them failed to warn of the known or

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[110] *Id.* (citation omitted).
[111] *Menard v. Newhall*, 373 A.2d 505, 506 (Vt. 1977).

knowable likelihood of injury including but not limited to the likelihood the user would develop abscesses, infections, and be forced to undergo corrective operations.

297. The Defendants designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied, labelled, and sold to distributors the ILS by Defendants, and each of them, was further defective due to inadequate post-marketing warning or instruction.

298. Plaintiff did not know, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. These defects caused the herein described injuries and damages as herein alleged.

299. The Defendants, and each of them knew that the aforesaid product was to be used by the user without inspection for defects therein and that the aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

300. Plaintiff neither knew, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defect.

301. As a direct and proximate result of Defendants' failure to warn, Plaintiff was injured, and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost wages, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

5th CAUSE OF ACTION
Fraud by Concealment

302. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

303. Vermont caselaw outlines that "in order to state a claim for fraud based on fraudulent concealment, a plaintiff must demonstrate: (1) concealment of facts, (2) affecting the essence of the transaction, (3) not open to the defrauded party's knowledge, (4) by one with knowledge and a duty to disclose, (5) with the intent to mislead, and (6) detrimental reliance by the defrauded party."[112]

304. At all times mentioned herein, Corporate Defendants had the duty and obligation to disclose to Plaintiff and to his physicians, the true facts concerning the aforesaid product; that is, that said product was dangerous, and defective, and how likely it was to cause serious consequences to users, including injuries as herein occurred.

305. Defendants made the affirmative representations as set forth above to Plaintiff, his physicians, and the general public prior to the date the ILS was used on Plaintiff while concealing the following material facts.

306. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff and to his physicians the true facts concerning the aforesaid product; that is, that use would cause injuries including but not limited to abscesses, infection, hemorrhages, additional corrective surgeries, and abdominal pain.

307. The concealment of these facts affected the essence of the transaction as Plaintiff's physicians would not have purchased the ILS and used it had they been aware of its true safety

[112] *Fuller v. Banknorth Mortg. Co.*, 788 A.2d 14, 16 (2001) (citations omitted).

profile. The concealment of these facts was not known to Plaintiff or his physicians and said concealment was made with the intent to mislead healthcare providers to purchase and use their ILS on their patients, including Plaintiff.

308. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have utilized the product during the Plaintiff's procedure on September 15, 2018. Plaintiff and his physicians therefore detrimentally relied upon Corporate Defendants' statements regarding the ILS when making the decision to purchase and use it.

309. As a result of the concealment or suppression of the facts set forth above, Plaintiff sustained injuries and asserts against Defendants, a claim for judgment for all compensatory damages including, but not limited to medical expenses and related costs, extreme physical and mental pain and suffering, mental anguish, disability, disfigurement, degradation, unnecessary loss of personal dignity, and lost wages, in an amount to be determined by the jury, as well as costs and attorneys' fees, plus costs and all other relief to which Plaintiff is entitled by law.

310. In doing the action herein alleged, Defendants acted with oppression, fraud, and malice and Plaintiff are therefore entitled to punitive damages in an amount reasonably related to Plaintiff' actual damages, and to Defendants' wealth, and sufficiently large to be an example to others, and to deter these Defendants and others from engaging in similar conduct in the future.

WHEREFORE, Plaintiff respectfully demands judgment in an amount in excess of the jurisdictional limits of this Court against all Corporate Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal

injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law.

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial.

C) for specific damages according to proof.

D) for Punitive and Exemplary damages according to proof.

E) for pre-judgment interest and post-judgment interest as allowed by law.

F) for reasonable attorneys' fees.

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

Respectfully Submitted:

Date: May 24, 2021

/s/ Michael J. Gannon, Esq.

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